IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Oleg Iliich Epshtein

Title of Invention : Method For Correcting Immune Responses

And Medical Agent

Date Filed : January 22, 2005

Scrial No. : 10/522,651 Examiner : Pak, Michael D.

Art Unit : 1646

DECLARATION UNDER 37 CFR 1.132

I, Vasilij Nikolayevich Nikolayev, do hereby declare as follows:

- 1. My name is Vasilij Nikolayevich Nikolayev. I am Ph.D. in Medicine. I am well-familiar with the art and science of homeopathy and homeopathic technology.
- Since 1987, I have been working in the field of homeopathy: 1987-1994 Center of Homeopathy of Ministry of Health of USSR; 1988-1994 Chief Editor of Ukrainian Homeopathic Journal; 1996-Present National Homeopathic Union, Ukraine.
- 3. I am not employed by Materia Medica Holding, nor am I employed by Dr. Oleg Epstein, the inventor of the above-identified 10/522,651 application.
 - 4. I reviewed the claims of the '651 application.
- 5. It is my understanding that the claims of the '651 application stand rejected as allegedly anticipated by U.S. Patent No. 5,698,195 to Le et al. ("Le"). In my understanding, the term "anticipate" means Le discloses the same invention as claimed in the '651 application, namely, a "homeopathically activated form" of antibodies to cytokines involved in regulating inflammatory process.
 - 6. I reviewed Le in its entirety.

- 7. "Homeopathic potentization" is a term with well-defined meaning in the art of homeopathy. It is generally understood as "creating the desired homeopathic potency" though homeopathic technology.
- 8. While different means of creating homeopathic potentization are known, it is my opinion as one skilled in the art of homeopathy that no process disclosed in *Le* would be expected to lead to homeopathic potentization.
- 9. It is my further opinion that no specific substance disclosed in Le is "homeopathically activated or potentized."
- 10. Therefore, it is my opinion as one skilled in the arts of homeopathy and homeopathic technology that *Le* does not disclose a "homeopathically activated" or "homeopathically potentised" form of an antibody.

All statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment; or both, under Section 1001 of Title 18 of the U.S. Code and that such willful false statements may jeopardize the validity of any patent application issuing thereon.

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Dated: November <u>4</u>, 2009